

APR 16 2010

510(k) Summary

Introduction	According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.
Submitter name, address, contact	<p>Roche Diagnostics 9115 Hague Road, P.O. Box 50416 Indianapolis, IN 46250-0416 317-521-3577</p> <p>Contact Person: Kelly Colleen O'Maine Adams Phone: 317-521-3577 Fax: 317-521-2324 Email: colleen.adams@roche.com</p> <p>Secondary Contact: Stephanie Greeman Phone: 317-521-2458 Fax: 317-521-2324 Email: stephanie.greeman@roche.com</p> <p>Date Prepared: March 17, 2010</p>
Device Name	<p>Proprietary name: Elecsys TSH CalCheck 5 Common name: TSH CalCheck 5 Classification name: Single (specified) analyte controls (assayed and unassayed)</p>
Predicate device	The Elecsys TSH CalCheck 5 is substantially equivalent to other products in commercial distribution intended for similar use. We claim equivalency to the currently marketed Elecsys CalCheck TSH (K963147).
Device Description	The Elecsys TSH CalCheck 5 is a lyophilized product consisting of TSH in equine serum matrix. During manufacture, the analyte is spiked into the matrix at the desired concentration levels.
Intended use	The Elecsys TSH CalCheck 5 is an assayed control for use in calibration verification and for use in the verification of the assay range established by the Elecsys TSH reagent on the indicated Elecsys cobas e immunoassay analyzers.

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510(k) Summary, Continued

Comparison Table

The table below compares Elecsys TSH CalCheck 5 with the predicate device, Elecsys CalCheck TSH (K963147).

Characteristic	Elecsys CalCheck TSH (K963147)	Elecsys TSH CalCheck 5
Intended Use	For use in the verification of the calibration established by the Elecsys TSH reagent on the indicated Elecsys and cobas e immunoassay analyzers.	The Elecsys TSH CalCheck 5 is an assayed control for use in calibration verification and for use in the verification of the assay range established by the Elecsys TSH reagent on the indicated Elecsys cobas e immunoassay analyzers.
Levels	Three	Five
Format	Lyophilized	Same
Handling	Reconstitute the contents of Check 1, Check 2 and Check 3 with exactly 1.0 mL distilled or deionized water. Allow the bottle to stand closed for 15 minutes. Mix gently by inversion to ensure homogeneity.	Reconstitute Check 1, Check 2, Check 3, Check 4, and Check 5 with exactly 1.0 mL distilled or deionized water. Allow to stand closed for 15 minutes, then mix gently by inversion.
Stability	<u>Unopened:</u> <ul style="list-style-type: none">• Store at 2-8°C until expiration date <u>Reconstituted:</u> <ul style="list-style-type: none">• 20 – 25°C : 4 hrs	Same
Matrix	Equine serum matrix	Same

Performance Characteristics

The Elecsys TSH CalCheck 5 was evaluated for value assignment and stability.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Roche Diagnostics
Roche Professional Diagnostics
c/o Ms. Kelly Colleen O'Maine Adams
Regulatory Affairs Consultant
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Food & Drug Administration
10903 New Hampshire Avenue
Building 66
Silver Spring, MD 20993

APR 30 2010

Re: k093836
Trade Name: Elecsys TSH CalCheck 5
Regulation Number: 21 CFR §862.1660
Regulation Name: Quality control material (assayed and unassayed).
Regulatory Class: Class I reserved
Product Codes: JJX
Dated: February 08, 2010
Received: February 12, 2010

Dear Ms. O'Maine Adams:

This letter corrects our substantially equivalent letter of April 15, 2010.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-5680 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'CCH', with a long horizontal line extending to the right.

Courtney C. Harper, Ph.D.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indication for Use

510(k) Number (if known):

Device Name: Elecsys TSH CalCheck 5

Indication For Use:

The Elecsys TSH CalCheck 5 is an assayed control for use in calibration verification and for use in the verification of the assay range established by the Elecsys TSH reagent on the indicated Elecsys and cobas e immunoassay analyzers.

Prescription Use X
(21 CFR Part 801 Subpart D)

And/Or

Over the Counter Use
(21 CFR Part-801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Carol Benson

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K093836